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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,500	11/19/2003	Jim E. Leone	MICRU-65282	8234

24201 7590 10/09/2007

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EXAMINER	
MENDOZA, MICHAEL G	
ART UNIT	**PAPER NUMBER**
3734	

MAIL DATE	DELIVERY MODE
10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,500	LEONE ET AL.	
	Examiner	Art Unit	
	Michael G. Mendoza	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6-19,21-35,37,39,40 and 44-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,6-19,21-35,37,39,40 and 44-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 5/23/2007 have been fully considered but they are not persuasive. The applicant argues the helical proximal portion of Ferrera et al. is used to fill and reinforce the distal, three dimensional shaped portion, and the non-linear anchor portion of the application is dimensioned to engage the vasculature for securing the occluding device in the vasculature. The limitiation of, dimensioned to engage the vasculature for securing the occluding device in the vasculature, is a functional recitation, and lacks sufficient structure. The vasculature of the body has many different dimensions, and depending of the location of the vasculature the helical proximal portion of Ferrera et al. would be dimensioned to engage the vasculature for securing the occluding device in the vasculature. Therefore Ferrera et al. reads on the claim limitations.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 6-19, 21-30, 40, and 44-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferrera et al. 6171326.

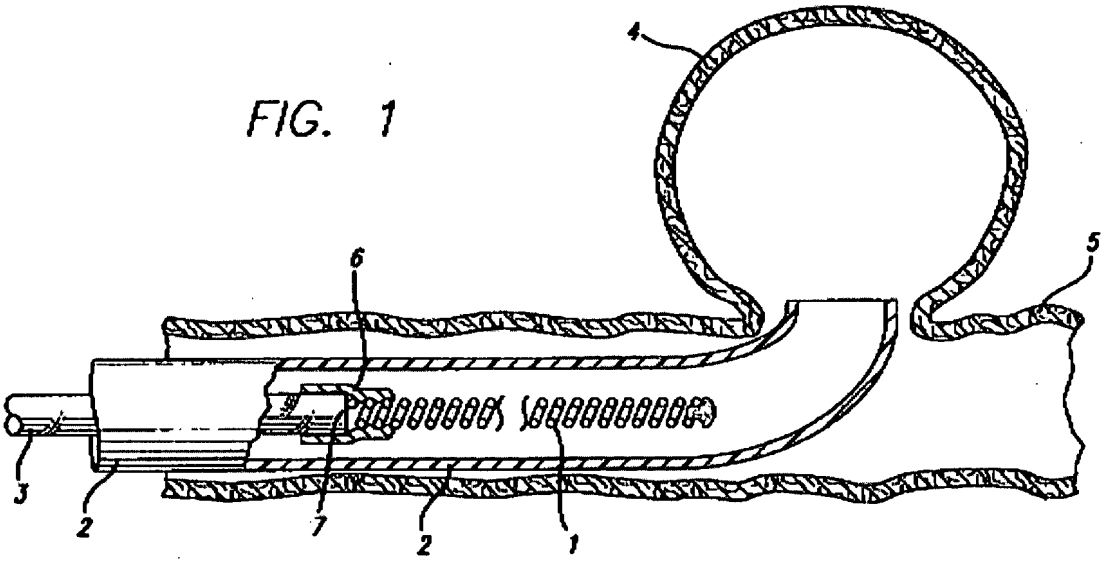
4. Ferrera et al. teach a vasoocclusive device comprising: at least one strand of a flexible material formed to have a first inoperable, substantially linear configuration for

insertion into and through a catheter to a desired portion of the vasculature to be treated, and a second operable configuration for framing or occluding the desired part of the vasculature to be treated, said operable configuration including a first portion configured to frame or occlude a part of the vasculature to be treated and a second non linear portion configured to engage an artery wall for securing the occluding device in the artery system of the vasculature; wherein the portion for securing the occluding device in an artery system of the vasculature comprises an anchor portion of the second operable configuration to secure the occluding portion of the device in the artery system of the vasculature; wherein the anchor portion comprises a plurality of extending loops along a longitudinal axis to thereby provide contact surface area for anchoring the occluding portion of the device in the artery system of the vasculature; a second portion having a first inoperable, substantially linear configuration for insertion into and through a catheter to a desired portion of the vasculature to be treated, and a second operable, coiled shape for filling and reinforcing the desired portion of the vasculature when the vasoocclusive device is implanted at the site in the vasculature to be treated; a second portion having a first inoperable, substantially linear configuration for insertion into and through a catheter to a desired portion of the vasculature to be treated, and a second operable, substantially helical coil shape for filling and reinforcing the desired portion of the vasculature when the vasoocclusive device is implanted at the site in the vasculature to be treated; wherein said at least one strand of a flexible material is a helical shape; wherein said at least one strand of a flexible material is a wire (see figures); wherein said flexible material comprises an alloy of titanium and nickel (col. 6,

lines 59-60); wherein said flexible material comprises a metal selected from the group consisting of platinum, palladium, rhodium, gold, tungsten, and alloys thereof (col. 6, lines 65-67); wherein said vasoocclusive device is formed from at least one flexible strand of a resilient radiopaque material to provide a radiopaque marker of the deployed configuration of a device made of the strand during vascular surgery; wherein said radiopaque strand comprises an alloy selected from the group consisting of platinum, tungsten and gold (col. 6, line 65-67); wherein said at least one strand comprises a super-elastic material; wherein said super-elastic material comprises a nickel-titanium alloy (col. 6, lines 59-60); wherein said at least one strand comprises a shape memory material; wherein said shape memory material comprises a nickel-titanium alloy (col. 6, lines 59-60); wherein the anchor portion is formed to reinforce the vessel in the vicinity of the damaged portion of the vasculature to be treated; the second operable configuration having an anchor segment further comprises at least one extending loop, the extending loop being curved about a longitudinal axis to form a hollow cylindrical circumferential pattern of loops about the longitudinal axis to provide a contact surface area to anchor the occluding portion of the device adjacent the artery system of the vasculature to be treated; wherein the second portion having a first inoperable, substantially linear configuration for insertion into and through a catheter to a desired portion of the vasculature to be treated, and a second operable configuration consisting of a coil segment further comprising, a coiled shape for filling and reinforcing the desired part of the vasculature when the vasoocclusive device is implanted at the site in the vasculature to be treated; the second portion having a first inoperable, substantially

linear configuration for insertion into and through a catheter to a desired portion of the vasculature to be treated, and a and through a catheter to a desired portion of the vasculature to be treated, and a second operable, substantially spherical configuration for occluding at least a portion of said vasculature to be treated, said substantially spherical configuration having about 90% of said strand in about the outer 15% of the diameter of said substantially spherical configuration (see figures).

FIG. 1



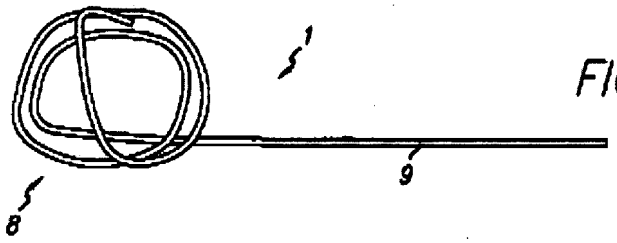


FIG. 2

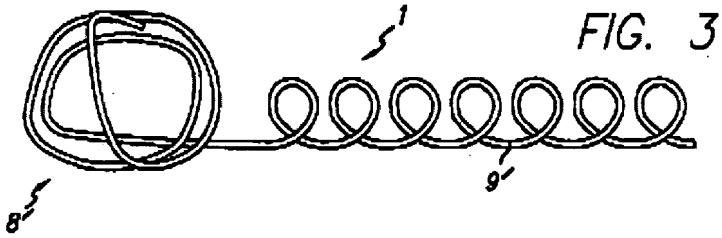


FIG. 3

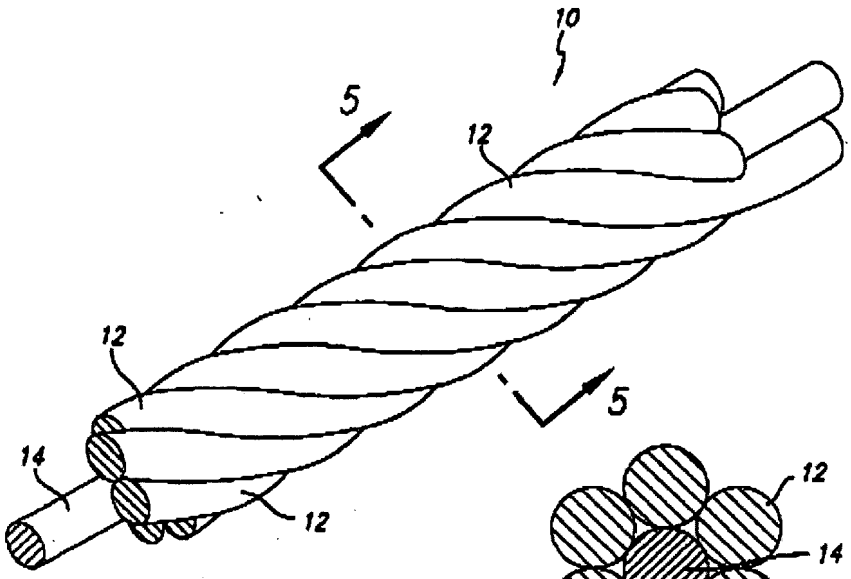


FIG. 4

FIG. 5

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 31-33, 37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrera et al. in view of Marks 5217484.

7. Ferrera et al. teaches the vasoocclusive device of claim 17. It should be noted that Ferrera et al. fails to teach an inner reinforcement member.

8. Marks teaches a device with a common inner reinforcement member for guidance of the device through a catheter. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the inner reinforcement member of Marks with the device of Ferrera to allow easy guidance of the vasoocclusive device through a catheter (col. 10, lines 39-49).

9. Claims 34 and 35 rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Ferrera/Marks as applied to claim 31 above, and further in view of Ken 5582619.

10. Ferrera/Marks teach the vasoocclusive device of claim 31. It should be noted that Ferrera/Marks fails to teach wherein the reinforcement member is coil shaped.

11. Ken teaches a device with a common coil shaped reinforcement member as alternate to a straight reinforcement member. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a coil shaped reinforcement member as an alternate to a straight reinforcement member because the coil shaped is a mere design choice and a mechanical expedient for reinforcing a vasoocclusive device.

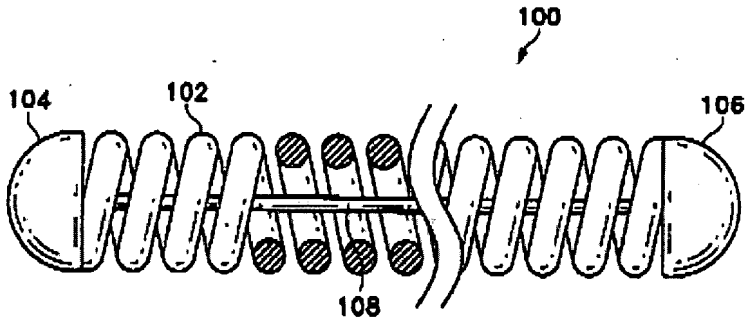


Fig. 1

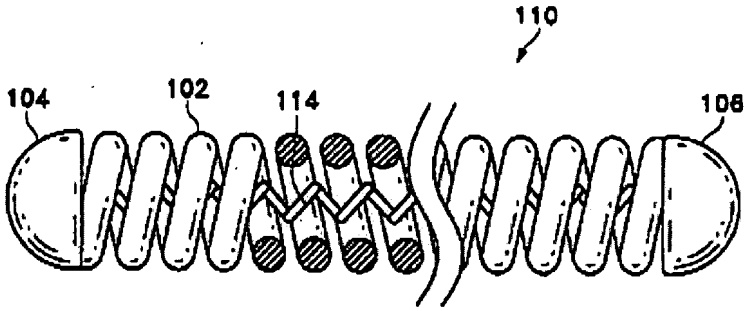


Fig. 2

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MM

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER